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09/516,078	03/01/00	HERTELENDY, PHARM.D.,PH.D Z	45061-8

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EXAMINER	
PORTNER,V	
ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/516,078	Applicant(s) Hertelendy et al
	Examiner Portner	Group Art Unit 1645

☒ Responsive to communication(s) filed on *Mar 1, 2000* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-20* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-20* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *2*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claims 1-20 are pending.

Priority

1. Priority to any prior Applications or priority documents has not been claimed at this time.

Information Disclosure Statement

2. The information disclosure statement filed April 17, 2000 has been considered prior to first Action.

Double Patenting

3. Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 6,099,853. Although the conflicting claims are not identical, they are not patentably distinct from each other because the now claimed inventions are directed to a genus of compositions and a genus of methods of using the compositions for stimulating an immune response and the allowed claims are directed to species of invention that are encompassed by the instant claims . Genus claims are obvious over the allowed species of invention.

Claim Rejections - 35 U.S.C. § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for formulation of suppository based compositions that comprises antigens and adjuvants for stimulation of an immune response in humans or animals, does not reasonably provide enablement for any and all antigens to be used in a suppository based delivery system for the stimulation of a protective immune response that prevents infection . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. .

The specification fails to teach how to formulate and use the claimed vaccines. The term "vaccine" encompasses the ability of the specific antigen to induce protective immunity to infection or disease induction. The specification teaches various sources for antigens to include viral, bacterial and microbial, and may include any type of cellular constituents to induce either cellular or humoral immune responses.

The specification does not provide substantive evidence that any antigen, in any amount, administered to any bodily orifice would be capable of inducing protective immunity. This demonstration is required for the skilled artisan to be able to use the claimed vaccines for their intended purpose of preventing infections caused by a pathogen of a human or animal. Without

this demonstration, the skilled artisan would not be able to reasonably predict the outcome of the administration of the claimed vaccines, i.e. would not be able to accurately predict if protective immunity has been induced.

The ability to reasonably predict the capacity of a single bacterial immunogen, or a single type of bacterial, viral or microbial cell, to induce protective immunity from in vitro antibody reactivity studies is problematic. Ellis exemplifies this problem in the recitation that "the key to the problem (of vaccine development) is the identification of the protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies"(page 572, second full paragraph).

Unfortunately, the art is replete with instances where even well characterized antigens that induce an in vitro neutralizing antibody response fail to elicit in vivo protective immunity. See Boslego et al. wherein a single gonococcal pillin protein fails to elicit protective immunity even though a high level of serum antibody response is induced (page 212, bottom of column 2). Accordingly, the art indicates that it would require undue experimentation to formulate and use a successful vaccine without the prior demonstration of vaccine efficacy.

The specification fails to teach the identity of what cellular constituents, as well as how these cellular constituents can be mutated, to induce protective immunity, albeit cellular or humoral immunity. Further, the specification fails to provide an adequate written description of the ~~any~~ many surface antigens, or nucleic acid sequences, that would induce a vaccine effect in any human or animal.

The skilled artisan would be required to de novo locate, identify and characterize the claimed antigens. This would require undue experimentation given the fact that the specification is completely lacking in teachings as to what single antigens, mutated antigens or combinations of antigens or mutated antigens that would contain the claimed characteristics and could be used in a method of inducing an immune response that prevents infection.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-20 recite Markush Groups of vaccine and vaccine adjuvants that are not so linked by a shared structure and function so as to define a proper Markush group. This rejection could be obviated by amending the claims to remove the phrase "selected from the group consisting of".

Claims 1, 2, 3, 13, 14, 16 recite the phrase "other antigenic determinants or combinations thereof". What these other antigenic determinants and combinations of these other antigenic determinants are is not distinctly claimed. Clarification is requested.

Claim 4 recites the phrase "is generated from known genetic information". What this information is, is not clearly set forth. It is not clear whether the genetic information is in the suppository or whether the antigen has been produced recombinantly and purified and then incorporated into the suppository or whether a host cell has been transformed with the genetic information which generates the antigen, wherein the host cell has been incorporated into the suppository. Clarification of what this phrase meets, and what the genetic information is, is requested.

Claim 13 recites the phrase "genetically engineered constituents of known pathogens selected from the group consisting of urogenital pathogens, anorectal pathogens and combinations thereof;". While one could determine what urogenital and anorectally pathogens were known at the time of filing the instant Application, what genetically engineered constituents are being used in the suppository-based vaccine delivery system is not distinctly claimed. The constituents are obtained from a Markush group of pathogens. The Markush group is improper, because virus', bacteria and fungal microbial pathogens, while they may share a common point of entry for causing disease, they do not share the same genetic material, nor do they produce all the same antigens. Removal of the phrase "selected from the group consisting of" is requested. Clarification of the constituents is requested.

Claim 14 recites an intended use "in humans or animals" but only recites a method step of inserting a suppository into a bodily orifice of a human. The method step of step (a) of claim 14

does not correspond to the full scope of the recited intended use of the method recited in the preamble of the claim. Clarification is requested.

Claim 14 defines the invention as a method of preventing urogenital or anorectal disease, but the antigens recited in the claims are not limited to antigens obtained from urogenital or anorectal disease causing pathogens. The claimed invention is not distinctly claimed.

Claim 14 administers any amount of antigen to a human to stimulate an immune response. The type of immune response can be any type of immune response and need not be prophylactic as recited in the preamble of the claim. The invention is not distinctly claimed through the recitation claim limitations that need not induce a protective immune response. The method as now claimed, is a method of inducing an immune response, not a method of preventing infection. Clarification of the invention is requested.

Claim 15 recites the phrase "other microbes or combinations thereof". What other microbes are intended if they are not urogenital or anorectal pathogens is not clearly pointed out. Are the other microbes intended to be urogenital or anorectal pathogens? The language used does not clearly recite that the microbial pathogens are urogenital or anorectal pathogens. Clarification is requested.

Claim 15 recites a clarification phrase "wherein the protein or nucleic acid originate from the genetic constituents".What this means is not clearly pointed out. Is this phrase defining the suppository-based delivery system to be a gene therapy composition that results in the production and expression of a protein? The phrase "nucleic acid" is recited in the singular. It should recite

the plural --acids-- for antecedent basis in claim 14 which recites the word "acids". Clarification of what is intended to be in the suppository administered is requested.

Claim 18 defines the polyethylene glycol suppository base to comprise polyethylene glycol and polysorbate. While this is very possible, it is confusing to define the polyethylene glycol suppository base as being polysorbate. This rejection could be obviated through deleting the phrase [polyethylene glycol] and define the "suppository base" as containing the recited components of polyethylene glycol and polysorbate.

Claim Rejections - 35 U.S.C. § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Please Note: The examiner is reading the word "bodily orifice" to include oral, vaginal, rectal and optical orifices to which a vaccine delivery system can be adapted to facilitate transfer of the material contained in the delivery system therethrough.

9. Claims 1-4, 6, 10-11, 14-15, 17 are rejected under 35 U.S.C. 102(b) as being anticipated by **Uehling et al** (June 1997, different inventive entity).

The claimed invention is directed to suppository based vaccine delivery system compositions that comprise a vaccine or vaccine adjuvant and methods of delivering the compositions to a host via a body orifice.

(Composition, Claims 1-4, 6, 10-11) Uehling et al disclose a vaginal suppository that is formulated in such a way that it could be used as a rectal suppository as well, wherein the suppository base comprised polyethylene glycol, polysorbate 80, depolarized gelatin and thimersol together with a whole cell vaccine of heat killed uropathogenic bacteria to include Escherichia coli, Proteus mirabilis, P.morganii, Enterococcus faecalis and Klebsiella pneumoniae (Materials and Methods section, col. 2, page 2049). The reference anticipates the now claimed compositions.

(Methods, Claims 14-15 and 17) Uehling et al disclose a method of stimulating an immune response in a human through inserting a suppository-based vaccine delivery system into a body orifice to induce an immune response in the human.

The reference anticipates the now claimed method of stimulating an immune response directed against urogenital or anorectal disease causing pathogens (see page 2051, Figure at top of column 1).

10. Claims 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by **Grinstaff** et al (US Pat. 5,639,473).

The claimed invention is directed to a method of preventing disease in an animal or human through administration of a suppository based vaccine delivery system that comprises nucleic acids, the method comprising insertion of the suppository and contact of the subjects mucosal tissue with the suppository.

Grinstaff et al disclose and claim a method that comprises administration of nucleic acids to a subject, wherein administration is accomplished through insertion of the suppository by the rectal or vaginal routes (see claim 26). The nucleic acids are derived from disease causing pathogens such as hepatitis (see col 40, line 9) or AIDS virus (see col. 40, line 10).

Inherently the reference anticipates the now claimed invention.

11. Claims 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by **Lockett** et al (US Pat. 5,854,224)

The claimed invention is directed to a method of preventing disease in an animal or human through administration of a suppository based vaccine delivery system that comprises nucleic

acids, the method comprising insertion of the suppository and contact of the subjects' mucosal tissue with the suppository.

Lockett et al disclose and claim a method that comprises administration of nucleic acids to a subject, wherein administration is accomplished through insertion of the suppository into a body orifice (see claim 28). The nucleic acids encode an antigen and the suppository facilitates improved uptake and expression of the nucleic acids encoding the antigen by cells of the tissue to which the nucleic acid/delivery complexes are applied, with subsequent stimulation of an immune response to the expressed antigen (see col. 9, lines 24-32).

Inherently, the reference anticipates the now claimed invention.

12. Claims 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Beck et al (US Pat. 4,756,907).

The claimed invention is directed to a method of stimulating an immune response in a human through insertion a suppository-based delivery system through a bodily orifice in such a way that the suppository is contacted with a mucosal surface.

(Methods claims) Beck et al disclose and claim a method of actively immunizing a human through insertion of a suppository based delivery system into a bodily orifice, wherein the suppository based delivery system (see claims 11, 21, and 26) comprises an antigen obtained from viral or bacterial pathogens (see claims 21-22, 56 and 61).

The incorporation of urogenital pathogen antigens into a suppository are taught to include Escherichia coli, Neisseria gonorrhea, Candida albicans, Haemophilus vaginalis, Herpes virus types 1 and 2 to name a few (see claims 21 and 22).

The dosage administered to the human is about 500 to 1000 micrograms per day, and a booster would be about 500 to 1000 micrograms within a 24 hour period (see col. 12, lines 1-4).

The reference inherently anticipates the now claimed invention.

13. Claims 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee (US Pat. 5,733,540).

The claimed invention is directed to a method of stimulating an immune response in a human through insertion of a suppository-based delivery system into a bodily orifice in such a way that the suppository is contacted with a mucosal surface.

(Methods claims) Lee discloses and claims a method of preventing infection caused by a pathogen through insertion of a suppository based delivery system into a bodily orifice, wherein the suppository based delivery system (see claims 20 & 24-26) comprises a transformed host cell expressing an antigen obtained from viral pathogen (see claims 16-19).

The suppository is inserted and contacted with a mucosal surface, upon which it adheres. The cells and antigens released from the suppository would stimulate a local immune response thereto, but the cells also serve to bind and inactivate pathogens entering the animal or human through the rectal or vaginal routes. The reference inherently anticipates the now claimed invention.

Claim Rejections - 35 U.S.C. § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 1-6, ~~14~~ 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over . Beck et al (US Pat. 4,756,907) in view of Singh (US Pat. 5,858,371).

The claimed invention is directed to a suppository based delivery system for stimulation of an immune response to an antigen obtained from a microbial pathogen, through insertion of the suppository into a bodily orifice of a human or animal.

(Compositions) See discussion of Beck above (US Pat. 4,756,907). Beck et al teach the formulation of a suppository-based antigen delivery system (see claims 11-22 and 26) for stimulation of an immune response in a human, wherein the suppository is capable of stimulating

an immune response when delivered through a bodily orifice, specifically the vagina or rectum (see col. 15, line 67).

The antigenic components are derived from pathogens, to include urogenital and anorectal pathogens, in a dosage form that provides the host about 500 to 1000 micrograms of antigen per day (see col. 12, lines 1-5 and col. 11, lines 10-33).

The suppositories are taught to comprise polylactic acid, polyglycolic acid, or copolymers of glycolic and lactic acids (see col. 12, lines 29-56 and claim 15), gelatin capsules (see col. 15, lines 59-61; col. 15, lines 1-38), or may be jellies, creams, foams or aerosols that also function as suppositories (see col. 16, lines 7-23).

The reference differs from the instantly claimed invention by failing to specifically show the suppository-base to be polyethylene glycol, polysorbate or combinations of polyethylene glycol, polysorbate.

Singh et al teach the use of polyethylene glycol and polysorbate (polyoxyethylene sorbitan fatty acid esters) and combinations thereof (see col. 5, lines 3-10) in an analogous art for the purpose of formulating and using a suppository-based delivery system for treating anorectal diseases (see claims 1-2, and all claims).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the suppository of Beck, to include polyethylene glycol and polysorbate in view of the teachings of Singh because Singh teaches that suppositories that comprise combinations of polyethylene glycol and polysorbate have application in the delivery of pharmaceutical compositions for anorectal and colonic disease and provide means for safe and painless application of suppositories for the realized effectiveness and delivery of agents to a host through an orifice (see col. 2, lines 38-40 and lines 43-52).

16. Claims 14-17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beck et al (US Pat. 4,756,907) in view of Azria (US Pat. ~~5,858,371~~ 5,149,537).

The claimed invention is directed to a method of stimulating an immune response to an antigen obtained from a microbial pathogen, through insertion of the suppository into a bodily orifice of a human or animal, wherein the suppository base comprises both polyethylene glycol and polysorbate and the polyethylene glycol has an average molecular weight of about 750 to 3700.

See discussion of Beck above (US Pat. 4,756,907). Beck et al teach a method of stimulating an immune response through inserting a suppository into a bodily orifice, specifically the vagina or rectum (see col. 15, line 67).

The reference differs from the instantly claimed invention by failing to specifically show the suppository-base to be a combination of polyethylene glycol and polysorbate, wherein the polyethylene glycol has an average molecular weight of about 750 to 3700..

Azria et al teach the use of a polyethylene glycol and polysorbate (polyoxyethylene sorbitan fatty acid esters) suppositories in an analogous art for the purpose of formulating and using a suppository-based delivery system (col. 1, lines 48-58), wherein the polyethylene glycol has an average molecular weight of about 3700, specifically 4000 .

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the suppository of Beck, to include polyethylene glycol and polysorbate in view of the teachings of Azria et al because Azria et al teaches that suppositories that comprise combinations of polyethylene glycol and polysorbate have application in the delivery of pharmaceutical compositions to body orifices and provide means for application of suppositories that are well tolerated by man (see col. 3, lines 45-46).

17. Claims 14 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beck et al (US Pat. 4,756,907) in view of Mizuno et al (US Pat. 4,462,984).

The claimed invention is directed to a method of administering a suppository based vaccine delivery system that comprises about 80% suppository base to a host that comprises an antigen obtained from a urogenital or anorectal pathogen.

See discussion of Beck et al (US Pat. 4,756,907) above. Beck et al show the formulation and teach the administration of suppository based vaccine delivery system that comprises antigen obtained from a urogenital or anorectal pathogen but differs from the instantly claimed invention by failing to show the suppository base to comprise about 80% of the composition.

Mizuno et al show a suppository base composition that comprises polyethylene glycol that contains about 80% by weight of polyethylene glycol in an analogous art for the purpose of delivering a component to an animal or human which has excellent moldability and storage stability.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the suppository base of Beck to contain about 80% suppository base because Mizuno et al show suppository base compositions that comprise about 80% by weight of polyethylene glycol which have excellent moldability and storage stability and the person of ordinary skill in the art would have been motivated to produce suppository based vaccine delivery systems that are stabile and readily moldable into the desired shape to aid in insertion of the suppository into an animal or human.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

19. Campo et al (US Pat. 6,174,532) is cited to show a suppository administered to a mammal for stimulation of an immune response to papilloma virus antigen (see claims 20, 16-18 and 21).

20. Harwood et al (US Pat. 4,439,194) is cited to show suppository drug delivery system that incorporates vaccine antigens (see col. 2, lines 66-68 through to col. 3, lines 1-2) and claim 3.

21. Ford (USPat. 5,466,463) is cited to show suppositories for encapsulation of bacterial cells.

22. Murch et al (US Pat. 6,046,179) is cited to show a suppository based delivery system that comprises an antigen (GAG) administered rectally to treat inflammatory bowel disease.

23. Liang (US Pat. 4,404,144) is cited to show rectal and vaginal suppositories that comprise polyethylene glycol, polysorbate and glycerin (Examples 18 and 19).

24. Marshall et al (US Pat. 5,840,318) is cited to show methods of stimulating an immune response using a suppository delivery system that comprises bacterial stress antigen and killed pathogens (see claims 5, 11 and 14).

25. Mor (US Pat. 5,096,940) is cited to show a degradable composition of polyethylene that is 90 to about 98% by weight that contains no more than about 1-5% polysorbate (see col. 8, lines 36-40 and claim 6).

26. Ekwuribe (US Pat. 5,681,811) is cited to show a polysorbate complex that comprises polyethylene glycol together with a physiologically active nucleoside that can be formulated into a rectal suppository with a suitable carrier (see col. 26, lines 6-7 and claims 1-3,29-30)

27. Bellani et al (US Pat. 4,894,237) is cited to show a dosage form that contains 20-80% polyethylene glycol and about 5% polysorbate by weight (see claims 5-7 and 16).

28. Neway et al (US Pat. 5,336,666) is cited to show a suppository that comprises Mycobacterium chelonae antigen used in a method of stimulating an immune response.

29. Pollock et al (US Pat. 4,863,900) is cited to show suppositories that comprises polyethylene glycol and polysorbate (see Example X, col. 7).

30. Purkaystha et al (US Pat. 5,002,771) is cited to show suppositories that comprise polyethylene glycol and polysorbate (see col. 11, lines 55-67).

31. Sekine et al (US Pat. 4,434,159) is cited to show a human suppository that comprises 90% by weight polyethylene glycol (example 5).

32. Whittaker et al (US Pat.5,906,922) is cited to show the use of a suppository for carrying nucleic acids to cells for transformation of the cells.

33. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp
April 5, 2001

L. R. F. Smith

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